UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/957,056	09/20/2001	Mark L. Tykocinski	285332-00002-2	6690

3705 7590 06/18/2002

ECKERT SEAMANS CHERIN & MELLOTT
600 GRANT STREET
44TH FLOOR
PITTSBURGH, PA 15219

EXAMINER	
HARRIS, ALANA M	
ART UNIT	PAPER NUMBER
1642	6

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/957,056	Applicant(s) TYKOCINSKI ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-50* is/are pending in the application.

4a) Of the above claim(s) *24-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23 and 37-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 23 and 37-50) in Paper No. 5, received March 1, 2002 is acknowledged.

2. Claims 23-50 are pending.

Claims 24-36, drawn to non-elected inventions are withdrawn from examination.

Claims 23 and 37-50 are examined on the merits.

Drawings

3. The drawings are objected to because of reasons cited on attached form PTO 948 completed by draftsman. Correction is required.

Specification

4. The first line of specification should reflect the current status of the parent nonprovisional application. A statement reading "This is a divisional application of Application No. 09/476,828, filed January 3, 2000, now U.S. Patent 6,316,256." should be entered as the first sentence of the specification.

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention (a cell with transferred proteins and the cancer vaccine comprising said cell) to which the claims are directed.

6. The use of the trademark FACStar® on page 10, line 21 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

7. The disclosure is objected to because of the following informalities: (a) the word "lethal" is misspelled on page 18, line 13; (b) in the "Brief Description of the Figures" Figure 2 is listed, however in the actual drawings there is Figure 2A and Figure 3A and Figure 3B is listed, however the actual drawings encompass Figure 3B and Figure 3C; and (c) the recitation "[???]" is not defined, not art recognized and appears to be a typographical error. Correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 37-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a cancer vaccine comprising a cell with a first protein (lipidated protein) and second proteins (several fusion proteins) to vaccinate subjects with L5178Y-R and T-50 tumor cells (see Examples 3-5, pages 17-19), does not reasonably provide enablement for the use of a cancer vaccine comprising several cell types in all types of cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants have provided data that supports the use of a cancer vaccine in mice with L5178Y-R murine lymphoma cells and T-50 tumor cells (tumor type not defined) in Examples 3-5 on pages 17-19. These examples, their accompanying figures 9-11 and figure captions on page 4 of the specification demonstrate the efficacy of the cancer vaccine before tumor challenge as well as after and during. Each of the two cancer vaccines comprised one cell type. The presented data is reflective of increased survival rates, enhanced immunoregulation and protective immunity in subjects with lymphoma and T-50 tumors. The specification does not sufficiently evidence the use of the two cancer vaccines for treatment of any and all cancer types, nor a cancer vaccine comprised of more than one cell type. Applicants have contemplated the use of the

claimed vaccine in cancer (not setting forth particular types), as well as autoimmune and alloimmune diseases including atopic allergy and organ rejection (page 8, lines 20-29). However, there is insufficient enabling disclosure supporting Applicants' contemplation. There is inadequate direction or guidance provided to assist one skilled in the art in the selection of which diseases and disorders that fall under the scope of cancer, autoimmune and alloimmune diseases that could be treated with the claimed vaccine with therapeutic effectiveness. Tumors are classified as immunogenic or non-immunogenic, solid or hematological in nature. Effective cancer strategies should be designed to deal effectively with the nature of each of these classifications. The specification does not teach how to extrapolate data obtained from observations set forth in the said Examples to the implementation of vaccination of any and all cancers, as well as autoimmune and alloimmune diseases. One cannot extrapolate the teachings of the specification to the plethora of disorders encompassed by the term cancer because it is well known that the art of anticancer drug discovery for cancer therapy is highly unpredictable, for example, Gura (Science 278:1041-1042, 1997) teaches that researchers face the problem of sifting through potential anticancer agents to find ones promising enough to make human clinical trials worthwhile (see first paragraph of page 1041). Further, the refractory nature of cancer to drugs is well known in the art and additionally complicated by drug medications that are composed of several agents. Jain (Sci. Am., 271:58-65, 1994) teaches that tumors resist penetration by drugs (see page 58, column 1, paragraph 2) and that "scientists need to put expanded effort into uncovering the reasons why therapeutic agents that show

encouraging promise in the laboratory often turn out to be ineffective in the treatment of common solid tumors", see page 65, column 3. It is clear that based on the state of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the claimed cancer vaccine functions as contemplated in the specification, i.e. broad treatment of cancer, alloimmune and autoimmune diseases. In addition, the vaccine formulation may not reach its target because of its inability to penetrate tissues or cells where its activity is to be exerted, may be absorbed by fluids, cells and tissues where the formulation has no effect, circulation into the target area may be insufficient to carry the formulation and a large enough local concentration may not be established. The specification provides insufficient guidance with regard to these issues. The specification also does not present sufficient working examples, which would provide guidance and significant preponderance of predictability to one skilled in the art the use of the claimed vaccine comprising more than one cell type would be therapeutically effective with a reasonable expectation of success. Furthermore, it appears that undue experimentation would be required of one skilled in the art to practice vaccination of all the disorders listed on page 8, line 9-19. Limited evidence has been provided which would allow one of skill in the art to predict the efficacy of the claimed vaccine's efficacy to confer protective immunity or generate an immune response in any and all cancers, autoimmune and alloimmune disorders with a reasonable expectation of success based on the analysis set forth. In view of the above, one of skill in the art would be forced into undue experimentation to practice implementation of the claimed invention.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 23 and 37-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 23 and 37 are vague and indefinite in the recitation "transferred protein". It is not clear from the method steps what is the transferred protein. While it is noted within the specification that the first protein, a lipidated protein coats the cell (see page 3, lines 28 and 29, page 5, lines 25-31), as well as the second protein, a fusion protein coats the cell (see page 7, lines 6-11). The claim does not specify which protein is regarded as the transferred protein. Applicants can obviate this rejection by amending the claims stating what is the transferred protein or proteins.

b. Claims 44 and 46 are vague and indefinite in the recitation "a costimulator". It is not clear from the text of the claim what molecule is to be costimulated. Accordingly, the metes and the bounds cannot be determined.

c. Claims 45 and 48 are vague and indefinite in the recitation "coinhibitor". It is not clear from the text of the claims what is to be coinhibited. Accordingly, the metes and bounds of the claims cannot be determined.

12. Claims 23 and 37-50 are free of the art.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.
June 3, 2002